UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

GOVERNMENT OF GUAM RETIREMENT FUND, on Behalf of Itself and all Others Similarly Situated, Plaintiff, v. INVACARE CORPORATION, *et. al.*, Defendants.	Case No. 1:13-cv-1165-CAB CLASS ACTION

LEAD PLAINTIFF'S RESPONSE TO
DEFENDANTS' NOTICE OF RECENT AUTHORITY

The Sixth Circuit's recent decision in *Kuyat v. BioMimetic Therapeutics, Inc.*, No. 13-5602, 2014 U.S. App. Dist. LEXIS 5738 (6th Cir. March 28, 2014) ("*BioMimetic*"), is off-point and provides no support for Defendants' motion to dismiss.

In *BioMimetic*, plaintiffs alleged that a biotech company misled investors by issuing "rosy assessments" of the prospects for FDA-approval of a new medical device that the defendant company wanted to bring to market. According to the plaintiffs, the FDA had privately communicated that it expected the company to obtain statistically significant results in clinical trials involving one population in order to obtain approval for the device, but that the company publicly characterized those results as less important than the company's analysis of a different population. *Id.* at *14. The district court dismissed plaintiffs' claims for failing to plead a strong inference of scienter, reasoning that defendants had a genuine basis for their

representations to investors because the FDA had issued a letter ***approving*** of the company's proposal to use its preferred population in the clinical trials. *Id.* The Sixth Circuit affirmed, agreeing with the district court's reasoning and noting that subsequent letters by the FDA were "ambiguous" regarding which population the FDA wanted the company to rely on. The Sixth Circuit further concluded that the company "fully disclosed the results of the study and told investors that the FDA wanted to see analysis of both [] populations." *Id.* at *17-18, 20.[1]

Here, Defendants' fraud has nothing to do with "ambiguous" letters from the FDA or "rosy assessments" about prospects for FDA-approval of a new product. Instead, the Complaint (and the FDA itself) alleges a 15-year history of clear, unambiguous FDA citations for ***recurring, serious, and systemic violations*** of the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations at Invacare. Moreover, unlike *BioMimetic*, here Defendants' scienter is made abundantly clear by the FDA's own Complaint For Permanent Injunction, which recounted the results of dozens of inspections at Invacare between 2002 and 2010, and confirms that Defendants were "***well aware*** that their practices violate[d] the [FDCA]" because the FDA "***repeatedly warned Defendants, both orally and in writing, about their violative conduct***." ¶246, Ex. 6. Significantly, many of the FDA's citations were for recurring violations of the same provisions concerning the same misconduct, which Defendants consistently ignored and refused to correct.

[1] In addition, the Sixth Circuit found that several additional factors supported the company's optimistic statements – ***factors that are absent from this action*** – including: (i) the FDA's prior approval of other devices based on similar analysis as the one preferred by the company; (ii) the company had already obtained regulatory approval for the device in both Canada and Australia; (iii) the company had previously succeeded in obtaining approval for a similar product; and (iv) an FDA advisory panel of experts subsequently "vindicated BioMimetic's optimism by voting to recommend that the FDA approve the device." *Id.* at *23.

Dated: April 4, 2014

Respectfully submitted,

/s/ Benjamin Galdston

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CERTIFICATE OF SERVICE

A copy of the foregoing was filed electronically this 4th day of April, 2014. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

/s/ Benjamin Galdston